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EAS

THE EUROPEAN ACCEPTANCE SCHEME FOR CONSTRUCTION PRODUCTS IN CONTACT WITH DRINKING WATER

Proposal of the Regulators Group on Construction Products in contact with Drinking Water

For presentation to
European Commission (DG Enterprise, DG Environment and DG SANCO)
Standing Committee on Construction (Article 19, Directive 89/106/EEC), and
Standing Committee on Drinking Water (Article 12, Directive 98/83/EC)

Note

The EAS Proposal has been prepared by the EAS Co-ordinating Group and discussed and supported by the Regulators Group on Construction Products in contact with Drinking Water (RG-CPDW). This proposal reflects the expert opinions of members of the RG-CPDW, the EAS Co-ordinating Group and the EAS Sub-Groups. It does not necessarily constitute a formal position of Member States or the European Commission with respect to the EAS.

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Executive Summary

Introduction

(1) This document describes the decisions and actions taken to date on the development of a European Acceptance Scheme for Construction Products in contact with Drinking Water (EAS) and sets out proposals of the Regulators Group on Construction Products in contact with Drinking Water (RG-CPDW)[1] on the structure and operation of the EAS. It goes on to identify those future decisions and actions that will be necessary to complete development work, to agree the final content of the EAS, and to manage its introduction. This Summary then highlights the principal decisions to be considered.

(2) The EAS Proposal has been prepared on request of the Commission[2] by experts nominated by Member States in close co-operation with the Commission, CEN and industry. The proposal is aimed to lay the foundation for further steps to be taken by the Commission in co-operation with Member States to establish, implement and manage the EAS.

Background

(3) Article 10 of Council Directive 98/83/EC (Drinking Water Directive, DWD)[3] requires from Member States "*to take all measures necessary to ensure that no substances or materials for new installations used in the preparation or distribution of water intended for human consumption or impurities associated with such substances or materials for new installations remain in water intended for human consumption in concentrations higher than is necessary for the purpose of their use and do not, either directly or indirectly, reduce the protection of human health provided for in this Directive"*. This article requires *de facto* from Member States to control the quality of products in contact with drinking water by a regulatory system for assessment and acceptance of these products.

(4) The objective of Council Directive 89/106/EEC (Construction Products Directive, CPD)[4] is to accomplish a single market for construction products. The CPD sets the legal framework for the CE marking of construction products that are fit for their intended use. The last part of Article 10 of the DWD refers to the CPD: "*The interpretative document and technical specifications pursuant to Article 3(1) and Article 4(1) of Council Directive 89/106/EEC shall respect the requirements of this Directive."*

(5) The existence in Member States of different systems for the approval of products in contact with drinking water creates barriers to trade and

[1] See footnote 6.
[2] In this document the European Commission is referred to as the Commission
[3] OJ L 330, 5.12.1998, p 32
[4] OJ L 40, 11.2.1989, p. 12

standardisation. This was also recognised in a CEN seminar in 1994 resulting in a recommendation to continue the standardisation work in a regulatory context.

(6) It is against this background that the Commission and four Member States (United Kingdom, Germany, France and the Netherlands) initiated in 1998 a feasibility study on the harmonisation of the four national schemes, as basis for a European scheme should be possible. The outcome of this study was positive. On basis of this study, and supported by the Standing Committee on Construction, the Commission decided to initiate the development of a European Acceptance Scheme (EAS).[5]

Development of the EAS

(7) The Regulators Group on Construction Products in Contact with Drinking Water (RG-CPDW)[6] was established by the Commission in 1999 to manage the development process. Since then, much has been accomplished, including:

- CEN Mandate M136 issued in May 2001
- Commission decision on the Attestation of Conformity published in May 2002[7]
- The EAS on Paper, interim report of the RG-CPDW, published for consultation in November 2001[8]
- EAS Research Programme 2001-2003[9]
- A Communication of the Services of the Commission outlining its approach to the EAS published in 2003[10]
- Elaborated assessment approaches for organic, metallic and cementitious products (draft final reports, November 2004).

EAS principles and the product assessment framework

(8) The principles underlying the EAS are:

- High level of consumer protection
- A sound scientific basis for the protection of public health, and an equal opportunity for putting products on the European Market
- Transparency of the EAS process.

[5] Documents RG-CPDW 001 (Feasibility Study) and RG-CPDW 002 (Consultation of the Standing Committee on Construction)

[6] The Commission has decided to restructure the RG-CPDW. The new official name will be Commission Expert Group on a European Acceptance Scheme for Construction Products in contact with Drinking Water. The (new) objectives and mandate of this group are expected to be ready in Spring 2005.

[7] OJ L 127, 14.5.2002, p. 16

[8] The EAS on Paper (doc. RG-CPDW 097rev) was put on the public website of the Commission (DG Enterprise) for consultation from August 2002 till March 2003

[9] On basis of the outcome of the research programme, the RG-CPDW concluded that GCMS-screening for unsuspected substances and the assessment of enhancement of microbial growth on basis of ATP measurements should be included in the EAS suit of tests.

[10] This communication was put on the public website of the Commission (DG Enterprise) in September 2003 and discussed in the Standing Committee on Construction in November 2003 (Doc. CONSTRUCT 03/627, Annex 2).

(9) The main elements of the EAS are identified in the EAS Proposal within the context provided by the CPD and the basis of the risk-based approach to product assessment is described. Details are given of the categorisation of materials, and of the proposed materials assessment process, built around the following key components:

- Provision of full information on the composition of materials making up the product
- Compliance of these materials with agreed Positive Lists, Composition Lists and Approved Constituents Lists.
- Initial type-testing of the product by way of a suite of tests applied as appropriate to cover:
  (a) Organoleptic aspects (odour, flavour and turbidity)
  (b) General hygiene (including TOC and chlorine demand)
  (c) Toxic substances (including DWD parameters, List substances and unsuspected substances)
  (d) Enhancement of microbial growth.

(10) The proposal examines the way these components are applied to test products made out of different material types. Different product types are described, together with the way materials assessment is related to product testing. Issues involved in product testing are reviewed.

Management of the EAS

(11) To operate effectively as a single scheme, certain tasks will need to be performed at the European level. These will include:

- Maintenance and continuing development of the EAS
- Provision of information on the EAS to users and producers
- Maintenance and updating of the Positive List, Composition List and Approved Constituent List
- Updating of test methods and technical specifications
- Assessment of issues referred by Certification Bodies
- Maintenance of databases of approved products
- Monitoring the consistent and effective performance of the EAS.

(12) Proposals are made for management and operational arrangements, and the resourcing requirements are outlined. Without the full detail of the EAS available it is impossible to estimate with any precision the costs that will arise from its operation. This Proposal identifies the different types and levels of cost that will arise, and outlines likely changes in the way cost burdens will fall.

(13) One of the conclusions in the EAS Proposal is that Council Directive 98/83/EC (DWD) should be amended to create a legal basis for the operation of the EAS[11] in addition to the existing legal basis for CE marking of construction products provided for by the CPD.

[11] This legal basis should also make it possible for the Commission Services to manage the EAS with support of Member States (See operational and managerial tasks referred to in paragraph 11).

Further actions

(14) Further actions will be required in future to fully detail and agree the methods of operation and implementation of the EAS. Future tasks include:

- Completion of the outstanding details of the Product Assessment procedures by the RG-CPDW Sub-Groups.
- Completion by CEN of test methods (and the related Commission sponsored research), and the harmonised product standards.
- Preparation of the EAS Manuals, which will detail the way the scheme operates for all participants
- Notification of Certification and Testing Bodies, and the establishment of a Forum of Notifying Bodies to promote high standards of common practice.
- Establishment of the management and organisational arrangements
- Introduction of the revised legal and regulatory regimes, both at European and Member State level.
- Design of transitional arrangements for the changeover from existing national approval systems to the EAS.
- Provision of information.

(15) Key decisions are identified, the most important of which will be the fixing (by a European decision) of acceptance levels, and the determination of a transitional programme to allow existing approved products to be brought within the scope of the EAS in a practical and economic manner.

(16) Recognition is made of the importance of keeping all stakeholders informed throughout the further EAS development and implementation processes.

Conclusions

(17) Sufficient work has been done, and been the subject of consultation in the RG-CPDW, for the framework of the product assessment procedure now to be formally agreed. There is a consensus in the RG-CPDW on the structure of the EAS, industry and Eureau[12] support the proposed EAS and there is adequate expertise in the EU to make the EAS work.

(18) The EAS has been developed in the context of the Construction Products Directive and the Drinking Water Directive, but it is now proposed that the Drinking Water Directive be amended to give explicit recognition to the role of the EAS.

(19) The character of the Scheme will require the establishment of management, technical and administrative capabilities at European level.

(20) It is now to all parties involved to take the necessary steps to finalise the development of the EAS, in particular:

- The Commission, to prepare, on basis of this proposal, amendments to the DWD and the Commission Decisions necessary to establish an appropriate

[12] Eureau = European union of national associations of water suppliers and wastewater services.

legal framework, to create a facility to operate the EAS and to take appropriate steps to facilitate the implementation of the EAS.

- Member States, to continue to work together on the development and the implementation of the EAS, and to prepare for the decision-making process at national and EU level.
- CEN, to continue the work on standardisation.
- Notified Certification Bodies, identified by Member States, to carry out the certification according to CPD and EAS requirements, to co-operate under the umbrella of the Group of Notified Bodies and to prepare the Certification Manual.

GLOSSARY OF ABBREVIATIONS

ACL	Approved constituent list for the European Acceptance Scheme
AoC	Attestation of Conformity; refers to the CPD system for attesting the conformity of construction products to European technical specifications
CEN	Comité Européen de Normalisation (European Committee for Standardisation)
CL	Composition Lists for the European Acceptance Scheme
CPD	Construction Product Directive (Directive 89/106/EEC)
CPDW	Construction Products in contact with Drinking Water
DG	Directorate General of European Commission
DWD	Drinking Water Directive (Directive 98/83/EC)
EAS	European Acceptance Scheme for CPDW
EFSA	European Food Safety Authority
EN	European Standard
EOTA	European Organisation for Technical Approvals
ETA	European Technical Approval
EU	European Union
GCMS	Gas Chromatography and Mass Spectrometry (analytical technique for identifying chemicals in leachates)
hEN	harmonised European Standard
MS	Member State of the EU
NAS	National Acceptance Scheme for construction products in contact with drinking water
NB	Notified Body (i.e. certification, inspection or testing bodies)
NCB	Notified Certification Body
PL	Positive List for the European Acceptance Scheme
RG-CPDW	Regulators Group on CPDW
SCC	Standing Committee on Construction (Article 19, Directive 89/106/EEC)
SCDW	Standing Committee on Drinking Water (Article 12, Directive 98/83/EC)
SCHER	Scientific Committee on Health and Environmental Risks
TC	Technical Committees of CEN
TDI	Tolerable Daily Intake
TOC	Total Organic Carbon
WHO	World Health Organisation

1. BACKGROUND AND WORK TO DATE

1.1. Rationale for an EAS

A number of Member States (MSs) operate national acceptance schemes (NASs) for products and/or materials used in contact with drinking water. These schemes involve testing of materials and products and/or the assessment of evidence for product acceptability, which may include recognition of test results from other countries. The test requirements, acceptance criteria and acceptance levels vary among the NASs. These different technical requirements constitute barriers to trade because MSs may require re-testing of products that have already been accepted in another MS in the European Union (EU).

As long ago as 1994 a CEN seminar concluded that the regulatory nature of national testing regimes was inhibiting the progress of standardisation. This conclusion prompted several delegations at the Standing Committee on Construction (SCC) to ask the European Commission[13] to set up a regulators group, similar to that established to deal with fire safety issues.

The third strand prompting change in this area is the provision made in 1998 in Article 10 of Council Directive 98/83/EC on the quality of water intended for human consumption (Drinking Water Directive, DWD)[14] requiring MSs to minimise the impact on drinking water quality of the materials and products used to construct new water supply systems. It should also be remembered that the increasingly stringent requirements of the Drinking Water Directive would in some cases require reductions in the contributions currently made by products in the water supply system if acceptance levels for drinking water quality are to be met. This pressure to improve some aspects of product performance would probably have required the modification and/or development of MS schemes. Whilst the duty was placed on MSs, there is obvious merit in moving towards common methods in order to avoid the duplication of development effort across Europe, and to promote uniformly high standards for protection for consumers.

1.2. Development of the EAS

In June 1998 the SCC established an informal group, lead by the Commission, comprising the regulatory representatives from France, Germany, Netherlands and United Kingdom to conduct a study of the feasibility of harmonising their respective NASs (the 4 MSs Feasibility Study)[15]. This study, conducted between September 1998 and March 1999, led to agreement on the outlines of a common acceptance scheme. This led to the decision to proceed with harmonisation initiatives for construction products in contact with drinking water (CPDW)[16].

[13] In this document the European Commission will be referred to as the Commission.
[14] OJ L 330, 5.12.1998, p. 32
[15] Document RG-CPDW 001 (Feasibility Study). All RG-CPDW documents are available on the CIRCA website (see Annex V).
[16] Document RG-CPDW 002 (Consultation of the Standing Committee on Construction)

The Regulators Group for Construction Products in contact with Drinking Water (RG-CPDW) was subsequently established as a working group of both the SCC and the Standing Committee on Drinking Water (SCDW). The aim of the RG-CPDW, which held its first meeting in June 1999, is to establish an EAS, using the outcome of the 4 MS Feasibility Study as a starting point and following recommendations of the SCC and the SCDW. The RG-CPDW comprises regulatory representatives and scientific experts appointed by MSs and representatives from relevant DGs of the Commission. Representatives from CEN, EOTA and trade organisations, including EUREAU, attend meetings as observers.

Since 1999 the RG-CPDW has managed a substantial programme of development work, and, together with the Commission, has issued some important decisions and consultation documents preparing the way for the introduction of an EAS. The work has been based on the legal, institutional and procedural framework provided by the Construction Products Directive (CPD)[17]:

- In May 2001 the Commission issued Mandate M136 to CEN. This set out the requirements seen at that time for the preparation of test methods for an EAS, and the drafting of harmonised technical specifications for products in contact with drinking water.
- In November 2001 the RG-CPDW issued an Interim Report (known as the EAS on Paper) on the structure and development of the EAS as a basis for consultation with all interested parties[18].
- In May 2002 the SCC approved the use (under the CPD) of the Attestation of Conformity (AoC) 1^+ System for the certification of products as regards their fitness for contact with drinking water[19].
- A conference on the EAS was held in Amsterdam in October 2002.
- In 2003 the Commission issued a formal "Communication Paper" setting out the latest view of the scope and operation of the EAS, which had been presented to the SCC.
- In 2003 the results were published of a series of research studies into the requirements for, and practicality of developing, test methods in several specific areas of product performance (see Annex V for the references to the final reports. The RG-CPDW took decisions on the elements to be introduced in the first phase of the EAS[20].
- The issues of materials testing were reviewed within the context of a consultation conference on the revision of the DWD.
- Throughout this time the RG-CPDW has received, and used as the basis of ongoing consultation, reports from specialist technical sub-groups established to examine and propose the approach to testing to be adopted for the different types of material in use in products.

[17] OJ L 40, 11.2.1989, p. 12
[18] Document RG-CPDW 097 (rev) (The EAS on Paper)
[19] OJ L 127, 14.5.2002, p. 16
[20] On basis of the outcome of the research programme, the RG-CPDW concluded that GCMS-screening for unsuspected substances and the enhancement of microbial growth on the basis of ATP measurements should be included in the EAS suite of tests.

1.3. Scope of the EAS

All CPDW, regulated in at least one MS, that may have an effect on the quality of the drinking water fall within the scope of the EAS. It should be understood that in this report the term drinking water is used instead of the more legally precise "water intended for human consumption" (as defined in the DWD), but has the same effect in covering the use of water for domestic purposes. Since the DWD applies to all water, either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes, the EAS will be applied to systems in buildings, including hot water systems.

Under the provisions of both the CPD) and the DWD, it is of the competence of the MSs to determine those parts of the water supply system that will be covered by the EAS. In all cases this will cover products used in the supply system from the point of treatment up to the consumer's tap.

When water is put into supply from sources where little or no treatment is required (e.g. wells and springs) the EAS will apply to construction products used for collection and control at the point of entry to the supply system. It is expected that in some MSs the EAS will be also applied to storage and conveyance of raw water, and to treatment works and equipment.

Examples of products used within water supply and storage systems are given below.

Products in contact with drinking water	
Polymeric sheet linings	Loggers/recorders*
Manufactured treatment equipment*	Cabling*
- filtration	Taps
- ion exchange	Flexible hoses (permanently installed)
- disinfection	Coatings and linings
- membranes	Water heaters*
Factory built tanks and cisterns	Hot water storage vessels
Pipes	Shower accessories*
Pumps	Water conditioning equipment*
Valves	Constituents of concrete, mortars and
Meters	grouts*
Probes*	Adhesives
Fittings, joints, sealings and gaskets	Lubricants*

** These items have subsequently been identified as not covered by the Mandate. The TC164 reply asked the Commission to consider their inclusion.*

Annex 1 of Mandate M136 to CEN defined the field of application of the EAS in terms of materials and products identified in the early stages of the development of the Scheme. M136 was linked to Mandate M131, Pipes and Tanks, to ensure consistency of approach to testing for mechanical characteristics, and to apply the AoC System 4 for the certification of these aspects of product performance.

Under the CPD, however, only products (not materials for further transformation) put on the market should bear the CE marking. Special arrangements will be made for the control of the constituents of concrete, etc. where CE Marking is not practical.

MSs regulatory arrangements will continue to apply to items and equipment used beyond the final tap.

(i) Devices attached beyond the consumer tap to process water for consumption are regarded as being covered by food regulations (Regulation EC 178/2002[21]).

(ii) Equipment used to provide temporary water supplies for events or emergencies.

1.4. Purpose of this Proposal document

This Proposal highlights the major policy decisions that now need to be taken, on the basis of all the work to date, to put in place the operating, legal and institutional framework for the EAS. It also sets out the decisions and actions that will still be required for the development of further detail, for the final endorsement of the EAS, and for planning its implementation.

This document does not repeat the detail of material that has previously been issued, or revisit decisions that have already been taken. Wherever necessary more information is given in appendices or in other references to documentation.

[21] OJ L 31, 1.2.2002, p. 1

2. LEGAL FRAMEWORK

2.1. Construction Products Directive (89/106/EEC)

Council Directive 89/106/EEC on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products (Construction Products Directive, CPD), as amended by Council Directive 93/68/EEC, sets the legal framework for the CE marking of construction products that are fit for their intended use. The wide role and function of the Directive is well understood, and is being applied to many product types in addition to those in contact with drinking water. The EAS relies on its legal, institutional and procedural framework. The only specific factor that is peculiar to the EAS is the proposed use of the EAS Logo (see paragraph 3.4).

2.2. Drinking Water Directive (98/83/EC)

Article 10 of the DWD (Quality assurance of treatment, equipment and materials) states that:

> *"Member States shall take all measures necessary to ensure that no substances or materials for new installations used in the preparation or distribution of water intended for human consumption or impurities associated with such substances or materials for new installations remain in water intended for human consumption in concentrations higher than is necessary for the purpose of their use and do not, either directly or indirectly, reduce the protection of human health provided for in this Directive. The interpretative document and technical specifications pursuant to Article 3(1) and Article 4(1) of Council Directive 89/106/EEC (-) shall respect the requirements of this Directive."*

Article 10 requires action on the part of MSs. The EAS will provide an appropriate control system that is based on agreed best MS practice. However, the DWD makes no reference to the EAS and, since responsibility is placed upon MSs, there is no reference to actions at the European level. This means:

- MSs will remain free to adopt the EAS, in whole or in part, on a voluntary basis. If MSs were to adopt a variety of different approaches to the use of the EAS, then the aims of the removal of barriers to trade, and of the protection of consumers at a uniformly high level, would be prejudiced. (See paragraph 3.5 (iii) and (iv)).
- It will be very difficult to put into place, resource, and sustain management arrangements at the European level without legal specific powers.

The RG-CPDW recommends that in any revision of the DWD the role and application of the EAS is included (see also chapter 4).

2.3. Nature of the legal powers required

The present DWD gives no explicit powers to establish and maintain the EAS. Without these powers it will be impossible to provide the staffing and budget to manage and administer the EAS at European level.

Powers are also required to give legal force to those aspects of the EAS that are not covered by the CPD (see paragraph 3.5). It will be appropriate to relate these powers to the existing Article 10. The RG-CPDW recommends that the provisions of the EAS be applied in all MSs without variation. If MSs were free to decide whether to adopt the Scheme, or to vary its provisions, even within a common framework, it would in effect recreate a variety of local schemes. This would have major disadvantages:

(i) It would allow barriers to trade to remain in place, and products would continue to require testing against the particular national requirements.

(ii) The work of producers and notified bodies would be made considerably more complex.

(iii) Producers would often face higher costs than might otherwise have been the case.

(iv) There would be varying levels of consumer protection, even though the EAS is designed to fulfil the requirements of the DWD.

(v) It will be more difficult to provide simple, clear guidance to users.

The EAS would fall well short of its aims if only common test methods and the system of attestation of conformity were adopted.

3. PRINCIPLES AND POLICY PROPOSALS FOR PRODUCT ASSESSMENT FOR THE EAS

3.1. Guiding principles for the establishment of the EAS

In addition to the harmonisation arrangements under the CPD (see paragraph 2.1), the RG-CPDW proposes a set of special features to control the impact on water quality of all products in contact with drinking water with the aim of protecting human health. This chapter sets out the principles, structure and proposed means of operation of the product assessment procedures of the EAS, distinguishing those normally operating under the CPD from those dealing particularly with the special features of the EAS.

Following the recommendation of the 4MS Feasibility Study, and in line with the EAS on Paper, the RG-CPDW has adopted the following principles in developing its proposals for the EAS:

- The EAS will offer a high level of consumer protection that does not compromise the existing protection levels of NASs.
- A sound scientific basis for the protection of public health, and an equal opportunity for putting products on the European market.
- All stages of the EAS-process will be transparent.

These principles are justified and explained in the following sections.

High level of consumer protection

The existing protection level of each NAS has been considered by the RG-CPDW in order to develop the European level of consumer protection. The process of harmonising acceptance criteria and acceptance levels is not straightforward because of the differences in approaches to setting acceptance levels.

Most NASs include some means of relating laboratory test results to actual product service conditions. However, the NASs also approach this in different ways, such as varying the test conditions, devising specific conversion factors, varying the acceptance limit and assuming either average or worst case service conditions. These differences make it particularly difficult to compare the level of protection offered by each NAS through comparison of their individual elements.

The level of protection offered by the EAS will satisfy the requirements to the protection of human health provided for in the DWD. In general, DWD parametric values have been set on the basis of the World Health Organisation (WHO) approach to derivation of guideline values for drinking water. In the EAS it is proposed to apply the same approach for parameters not controlled by the DWD but required today under existing NASs. However in determining the acceptable contribution of a construction product to the overall concentration of a parameter, account will be taken of the following factors:

- Product surface area in contact with drinking water
- Potential for extended contact with drinking water

- Product location in the water supply system
- Contribution of the parameter from source water, treatment and other components of the water supply system.

In addition to the initial assessment of product performance, the EAS will enhance consumer protection by the adoption of the most demanding provisions of the CPD on Attestation of Conformity (System 1^+)[22].

The use of CE marked products will not in itself protect water quality if other aspects of the design and operation of water supply systems are not taken correctly into account. These aspects include:

- Systems design, operation and maintenance
- Installation practices, particularly for piping systems and the use of site-applied products
- Observance of good practice or regulations.

Attention to the above aspects is essential for water quality protection. They will often be the subjects of MS regulation. The RG-CPDW also supports the inclusion of references to relevant standards and codes of practice in the informative annexes of the hENs.

It should also be noted that the performance of some types of material can vary according to the nature of the water being conveyed. For example, there will normally be greater leaching from metallic products that are in contact with water with a low pH. The testing of products under the EAS aims to cover their performance in demanding conditions, but it would be unreasonable to assess performance in situations that are not representative of the majority of operating environments. There will be locations where the character of the drinking water is such that it would be undesirable to use certain approved products because unacceptable contamination might occur. In these situations it will be for MSs, in conjunction with local water suppliers, to issue guidance, or introduce local regulations, aimed at controlling the use of products with this risk potential in the areas concerned.

A sound scientific basis for the protection of public health, and an equal opportunity for putting products on the European market

It is intended that all CPDW will be subject to appropriate testing to meet consistent requirements on consumer protection. The different chemical constituents and behaviour in service of organic, metallic, and cementitious materials, mean that different test requirements, acceptance criteria and acceptance levels are needed for each material type.

This will mean that within the same general framework for the assessment of products, certain aspects may be emphasised or discarded, having regard to the nature and performance of the material employed in the product (see also paragraph 3.7). Such variations will recognise, among other things:

[22] See Annex III of Directive 89/106/EEC.

- The character of any substances leaching from the product, with special emphasis on those substances that are toxicologically relevant.
- The performance characteristics of the product over time, e.g. distinguishing declining from sustained release profiles.
- The elimination of certain risks if other relevant performance criteria are met e.g. acceptable metal concentrations would preclude the appearance of colour.

Transparency of EAS process

All aspects of the EAS development and implementation will be conducted as openly as possible. The RG-CPDW comprises representatives from relevant DGs and regulatory authorities of MSs and scientific experts appointed by the MSs. Observers from the trade organisations concerned as well as from CEN and EOTA participate at meetings. Members and observers have access to documents placed on the RG-CPDW Internet site. As further measures to ensure transparency, the EAS on Paper report[23] the EAS Conference[24] and the European Drinking Water Seminar[25] provided ample opportunities to allow stakeholders to submit opinions on the proposals for the EAS. It should also be remembered that the processes of CEN for the preparation of technical specifications emphasise participation of stakeholders.

Following implementation, the same principles of transparency will apply to the operation of the EAS. However, some provisions will be made for guaranteeing the confidentiality of product information, where this is necessary. This is in line with current practice.

3.2. Basic framework of the EAS

The 4MS Feasibility Study and the EAS on Paper proposed a number of key elements that would make up the framework for the examination and approval of products in contact with drinking water. Three categories of assessment were foreseen:

Control of the performance of substances and materials

(i) Creation of lists of acceptable substances for use in making organic, metallic and cementitious materials and products.
(ii) Provision by manufacturers of full formulation information for comparison with these lists.

Product testing (initial type testing), including

(i) Assessment of formulation (against PL or CL)
(ii) Organoleptic assessments
(iii) General hygiene assessments
(iv) Measurement of PL substances
(v) DWD parameters (indicated by formulation data)
(vi) Gas chromatography mass spectrometry (GCMS) for unsuspected compounds
(vii) Enhancement of microbial growth

[23] Document RG-CPDW 097rev
[24] International Conference CE-EAS: Almost a reality? Amsterdam, October 2002.
[25] Seminar on Drinking Water. Brussels, October 2003

(viii) Cytotoxicity

Auditing

(i) Pre-certificate audit of internal quality control systems

(ii) Post-certificate auditing of systems and products to ensure continuing conformity (including audit testing).

The largest part of the work of the RG-CPDW has been to take this prototype, and to design an effective acceptance scheme. This chapter sets out the overall framework now proposed in relation to the harmonisation provisions of the CPD. It then goes on to examine the product assessment principles in more detail.

3.3. Harmonising product assessment requirements under the CPD

The CPD provides the primary legal framework, institutional arrangements and procedures for harmonising product assessment requirements. These may be summarised as follows:

- Compliance with harmonised technical specifications. These specifications, generally harmonised European product standards, will set out the testing and certification requirements that producers must comply with to be able to place the CE Marking on their products.
- The harmonised standard will describe the systems of AoC to be followed. For products being tested for fitness for contact with drinking water under the EAS, the CPD System 1^+ provisions apply[26]. This requires a notified body to certify the producer's factory production control system, to carry out the initial type testing, and to arrange subsequent surveillance and audit testing. The 1^+ system of AoC provides the pre and post certification quality assurance that was sought by and explained in the EAS on Paper. For products also being assessed for mechanical performance, System 4 applies (by reference to M131); with type testing carried out by the manufacturer, but reviewed by the certifying body as part of the overall certification (see also Annex I)[27].
- Use of harmonised test methods.
- The harmonised standard will also describe what is required in terms of provision of product information, and the placing of the CE Marking.

It should be noted that, in the area of product marking, the RG-CPDW is proposing that an EAS Logo should be used in addition to the CE Marking. This is of considerable importance to ensure that such products are readily recognisable with a visible mark, particularly in retail market situations and where products may have alternative uses in additional to those concerned with water supply. The RG-CPDW has been advised that precedents do exist for the use of such a logo, but the proposal for an EAS Logo is specifically drawn to the attention of the SCC for endorsement.

The way in which the CPD is used to underpin the EAS is set out in Mandate M136, which addresses the items set out above. It should also be appreciated that use of the

[26] OJ L 127, 14.5.2002, p.16.

[27] See for more details CPD Guidance Paper K: The attestation of conformity systems and the role and tasks of the notified bodies in the field of the Construction Products Directive. Doc. CONSTRUCT 00/421, revision September 2002.

CPD framework also involves use of the institutional arrangements for product certification and conformity control using notified bodies. Practical development of the detailed operating arrangements of the EAS will have regard to the extensive body of guidance developed by the Commission and by CEN.

3.4. Special features of the EAS

The EAS incorporates a number of regulatory features that are not normally covered by the provisions of the CPD (see chapter 2 for legal background). Mandate M136 issued under the CPD makes reference to "fitness for contact with drinking water" characteristic. Certification of a product under this characteristic requires approval under the EAS, which as a regulatory scheme has features not found within the CPD.

The special features of the EAS are:

(i) Range of products covered. The EAS will cover some products that come into contact with drinking water that are not normally included in the product families of the CPD used for building regulation purposes. However, they do conform to the wider principles of the CPD in that they are regulated in one or more MSs, and they are permanently incorporated in building works.

(ii) Control of product constituents. The EAS will require detailed information to be given on the composition of products for comparison with Positive Lists (PLs), Composition Lists (PLs) and Approved Constituent Lists (ACLs). Whilst this is not usual under CPD arrangements, it can be justified as follows
- Preliminary screening against approved lists reduces testing requirements.
- Several MSs employ such controls at present, and failure to harmonise practice at European level would maintain barriers to trade.

(iii) Full suite of tests to be adopted by all MSs. The aim of the RG-CPDW is that all MSs adopt the full testing regime to maximise the protection of consumers across Europe, and to avoid detailed differences in the operation of the EAS that would complicate the placing of products on the market.

(iv) Adoption of common European acceptance levels. The CPD normally provides harmonised test methods, but MSs fix performance or acceptance levels. The aim of the EAS is to use the same acceptance levels in all MSs, for the same reasons as using a common test programme.

Whilst the assessment programme for products covered by the EAS indicates their fitness for contact with drinking water under demanding, but realistic, operating circumstances, it would not guarantee their performance under exceptional conditions. Where such conditions of use are anticipated, special measures may be needed by MSs to give guidance on, or control, the use of the product (see paragraph 3.2 for special water quality situations).

A summary of the steps in the EAS approval process is set out in Annex I.

3.5. Product assessment principles

Key definitions

In determining the principles of product assessment it is important to be as precise as possible about the meaning of frequently used terms. The following definitions have been agreed for the EAS.

Substance:	Chemical or mixture of related chemicals used to make a material.
Constituent:	Ingredient used to make a material or product.
Material:	Prepared form of a substance, or of a combination of substances, suitable for use in a manufacturing process.
Material type:	Category of materials of similar physical/chemical characteristics (e.g. organic, metallic).
Product:	Item made from a material or combination of materials or material types, in the form in which it is placed on the market.

Products may comprise a single material (e.g. a plastic pipe), or be made up of components of differing materials (e.g. a water meter with organic and metallic components). Since different material types have different interactions with water quality, it is necessary to subject product components of different materials to appropriate forms of testing. However, while components may be individually tested, it is the product itself that is assessed overall and certified in accordance with the provisions of the relevant harmonised product standard (or ETA).

Special arrangements are being made to cover site prepared and site applied materials, where the products placed on the market are used as inputs to the final application.

A risk based approach to the principles of product assessment

The approach to product assessment is based on an analysis of the risks posed to water quality by the products (including their constituent components) operating within the environments found within water supply systems.

The product assessment process is directly related to the risk of deterioration of drinking water quality from the leaching of substances from the products used in the supply and storage systems. Two risk factors determine the way the assessment process is structured, and the way product acceptance is determined:

- The potential of the material(s) incorporated in the product to leach harmful substances that pose a risk to health or produce unacceptable taste, odour or appearance.
- The likely extent and impact of leaching from a product having regard to its location and function in the water supply system.

The risk control strategy for the first of these factors itself comprises three elements:

(i) Provision, when products are submitted for approval, of full details of the formulation of the materials incorporated in the product.

(ii) Acceptance only of substances and materials that have been previously approved as having acceptable impacts on water quality. These would

appear in PLs (organics) or CLs (metals) and ACLs (cementitious), having been subject to toxicological assessment.

(iii) Testing of products to ensure that they have been produced as specified, and that their behaviour in contact with drinking water is acceptable.

The location and function of products determine the level of risk it poses to the quality of drinking water (2nd risk factor). This can be assessed by taking into account:

(i) The extent of the product's contact with drinking water, relating its surface area to the volume of water at the point of contact (the surface/volume, or S/V ratio).

(ii) The length of time any particular body of water is in contact with the product (the residence time). If water is static in the system for a length of time, there is a greater chance of a build up of a substance leaching from a product than if water is passing by at some speed.

This aspect of assessment is taken into account in the way laboratory leaching test results are related to the operating situation of the product, using conversion procedures related to S/V ratios and residence times. The results are then assessed against the agreed acceptance levels.

As a broad generalisation, products used within buildings pose more risk than those used in the public supply systems. This is because surface to volume ratios are higher, it is more likely that longer periods of stagnation will occur within buildings, and higher temperatures can affect leaching characteristics.

Use of Positive Lists, Composition Lists and Approved Constituent Lists

The "first line of defence" of the EAS will be the scrutiny of formulation and composition data in materials in products submitted for approval. Only listed substances or materials (i.e. those that have been assessed and shown to be safe, provided any specified restrictions are satisfied) will be permitted. Un-listed substances or materials will cause the product to be rejected. The EAS will be set up with inputs from current practice at European and MS level. This information will be subject to appraisal and confirmation over a limited transitional period after EAS implementation (see Annex II, section 5).

New substances proposed for addition to lists will be required to undergo rigorous examination. In the case of organic substances this will require the provision of toxicological information for independent evaluation. New metallic materials (compositions) will be subject to long-term testing to establish their impact on water quality. For cementitious materials, lists of Approved Constituents will be compiled (see Annex IV).

Provision and appraisal of information on materials making up products

Full details of the formulation of the constituents of products (chemical names and amounts of ingredients, major impurities and/or reaction products) are required to establish if a PL, CL or ACL covers it, and against which parameters (DWD and additional) it needs to be assessed by the certification body.

3.6. Framework for testing materials used within products

This section describes the steps in assessment to be carried out to ensure that drinking water, after contact with the materials making up a product, poses no significant risk to health, complies with the aesthetic parameters of the DWD, and minimises contamination as required by Article 10 of the DWD. Not all of the assessments and conditions apply to all products. This framework is based on the EAS on Paper, and incorporates the findings of the 2002-2003 research programme. In considering the research findings the RG-CPDW:

- Supported proposals for GCMS and microbial growth testing.
- Took the view that cytotoxicity testing could not be included in view of the time required to develop a test following further research. It may be appropriate to introduce this assessment after the implementation of the EAS in its initial form.
- Decided that testing under conditions of chlorination that simulated a high level of disinfection (e.g. of newly installed piping) could not be justified.

Organoleptic assessments

These assessments ensure that the appearance of drinking water is satisfactory and it is pleasant to drink. The DWD requires that odour, flavour, colour and turbidity of drinking water must be acceptable to the consumers and that no abnormal changes occur.

Odour and flavour

Abnormal odour and/or flavour are an indication of major degradation of water quality. Although bad odours and flavours can be generated by other sources, such as contamination of the drinking water source, experience has shown that CPDW can readily cause significant problems. Some materials have the capability of leaching into drinking water substances at very low concentrations (often undetectable analytically) that give rise to unacceptable odour and flavour. Testing to ensure that products do not lead to such contamination is a major part of any acceptance scheme.

Colour and turbidity

Products can lead to problems of objectionable colour and turbidity in drinking water. Consequently an assessment to control such problems is included in the EAS.

General hygiene assessments

Total organic carbon (TOC)

TOC can provide an estimate of the total organic matter in migration water. Following MS practice, an assessment of TOC is included in the EAS with a specified limit value to improve general hygiene.

Chlorine demand

The EAS includes a limit on the reaction of the product with chlorine in water. This assessment is included in order to ensure that products are relatively inert.

Metallic products – surface residues
A number of tests will be needed to assess the acceptability of a product in terms of the desired surface characteristics e.g. removal of grease films from fittings or, removal of surface layers of lead from brasses.

Substances that pose a risk to health

Drinking Water Directive parameters
Chemical parameters, as specified in the DWD, shall be assessed if their presence is indicated during the examination of the product formulation.

Positive List substances for organic materials
Substances in the formulation are measured to ensure that migration limits are not exceeded. TOC measurement, subject to the determination of a satisfactory procedure, will be used to avoid the need to analyse for a PL substance that a measured TOC level shows cannot exceed its DWPLL: i.e. it shows there is not enough organic matter present.

Unsuspected organic substances
An assessment for unsuspected organic substances will be carried out to reveal the presence of any chemicals in a product that are not indicated by formulation information. Such substances are detected by a procedure based on gas chromatography and mass spectrometry (GCMS). GCMS assessment was examined in the first EAS Research programme, and its practicality and usefulness confirmed. However, more research is required to ensure that the method can be used consistently, and that the interpretation of results will be uniform.

Metallic Composition List items
Tests for the compliance of the product with the accepted composition list.

Enhancement of microbial growth

Minimal amounts of organic material in water supply products can provide the food source for microorganisms. Any significant growth in the numbers of such organisms can lead to both aesthetic problems and health risks.

Tests to establish the potential of materials to enhance microbial growth are used in some MSs. Consequently, a standard procedure is to be incorporated in the EAS. The 2002/03 EAS Research Programme established the acceptability of the Dutch method that measures adenosine triphosphate (ATP) as an indication of the concentration of active biomass. More research is to be carried to improve the reproducibility of the method and to assist in the setting of acceptance levels.

3.7. Application of assessment principles to different material types

Products and product components may be made up of the following material types, each of which requires a different approach to testing:

- Organic materials (plastics, polymers, rubbers, resins, etc.)
- Metallic materials (pure metals and alloys)

- Cementitious materials (e.g. concrete, mortars, grouts, etc.)
- Glassy materials (Enamels)
- Other materials (including bitumen and lubricants).

Proposal for a matrix for EAS compliance criteria and testing related to material types (1)

EAS compliance criteria	Organic(2)	Metallic(3)	Cem'titious	Glassy
Positive lists	Yes	-	Yes	-
Composition lists	-	Yes	-	Yes
Approved Constituent list	-	-	Yes	-
Organoleptic tests				
Odour and flavour	Yes	-	Yes	-
Colour and Turbidity	Yes	-	Yes	-
General hygiene assessments				
TOC	Yes	-	Yes	-
Chlorine demand	Yes	-	To be decided	-
Surface residues (metals)	-	Yes	-	-
Substances posing a risk to health				
DWD parameters	Yes	Yes	Yes	Yes
PL substances	Yes	-	Yes (4)	-
Unsuspected substances (GCMS)	Yes	-	Yes (4)	-
CL compliance	-	Yes	-	Yes
Enhancement of microbial growth	Yes	-	Yes (4)	-

(1) No proposals have yet been made for other materials.
(2) Some specific exceptions
(3) Metals will not be subject to organoleptic testing because it is generally accepted the if DWD limits are met, organoleptic problems are unlikely to arise
(4) Depending on composition (see Annex IV)

The general framework for product assessment applies in principle to all types of material. However, not all elements of the testing programmes need be applied. This is because the nature and behaviour of materials does differ, and there is no purpose in applying inappropriate tests merely to be procedurally consistent. The tests to be applied within the overall framework will be related to the specific risks seen to arise from the character of the material. This will mean that some of the processes, criteria and factors that have been designed to be relevant to one material type (e.g. plastics) will be different to those used elsewhere (e.g. metals). The principle of equal opportunities for placing products on the market does not mean that all products and materials are treated the same. It does mean that all materials are assessed by a common approach, but using only those tests relevant to their risk potential.

The work of recommending the approach to product assessment in this general framework has been carried out by three Sub-Groups of the RG-CPDW. A great deal of technical detail is contained in the reports provided by these Groups. Many of the principles proposed by the Sub-Groups have been adopted by the RG-CPDW. Summaries of their proposals are set out in Annex II (Organic Products), Annex III (Metallic Products) and Annex IV (Cementitious Products).

In each of these areas of work points of detail remain to be researched, discussed and agreed (see paragraph 6.2), but these are not now seen to prevent the adoption of the principles on which the assessment processes will be based.

3.8. Testing related to product types

Type of products

Products have different functions and characteristics which pose different levels of risk, and which will influence the approach to be taken to product assessment:

- *Single material products*. Such products are relatively straightforward to test, using either the product itself, or a representative sample in the case of a large item.
- *Assembled products*. These products comprise two or more components, possibly of different materials. Where the components are of different materials, it may be necessary to separately measure their impacts on water quality. This may require the product to be dismantled, but in some situations it will be proper to test the complete unit in its intended conditions of use.
- *Multi-layer products* (including products with factory-applied coatings or linings). Where there is a foreseeable possibility that the layers not initially intended to be in contact with water may, within the expected life of the product, have an impact on water quality, each layer should be independently tested. (This situation might arise from migration through layers, or by the long-term deterioration of the layer intended to be in contact.) Where such an indirect action is not possible, e.g. because of the existence of a functional barrier, the layers that will not be in contact need not be tested.
- Site applied products. Products such as coatings and linings are placed on the market as ingredients that will be mixed and applied on site. Samples of such products, made up under simulated conditions of use according to the manufacturer's instructions and representing the product when it is brought into use, will be tested.

For example, where a single product consists of two (or more) separately packaged items, the individual items are analogous to components in "kits", with CE marking applied to the overall product[28]. Special arrangements are being made for concrete, mortars, etc. (see Annex IV).

[28] See CPD Guidance Paper C. The treatment of kits and systems under the Construction Products Directive. September 2002. Doc. CONSTRUCT 96/175 Rev. 2

Factors to be taken into account in product testing

The existing MS approval schemes have detailed protocols governing the procedures for product testing, particularly for complex products comprising different material types. Their aim is to balance the need for thorough testing against the level of cost to producers, and avoid unnecessary testing where:

- The formulation and performance of the constituent materials is well understood and has been approved for use in similar applications.
- The function of the product is such as to have only an insignificant impact on water quality.
- An updated product has only minor variations in composition or components from previously approved models.

The RG-CPDW is currently (December 2004) reviewing existing arrangements in MSs to determine "best practice" covering:

- Recognition of existing approvals for materials and/or components.
- Possibility of using an "approved materials" list.
- Limited testing where only minimum changes have been made to formulation, or where only individual components have been replaced.
- Acknowledgment that products within "families" (e.g. taps, valves) may conform closely to specifications that have been previously approved.
- Use of limited testing where the experience of product performance in known operating environments is such that the only essential screening need be carried out.

This work will provide an important input for the Certification Manual.

Test methods and the Certification Manual

Set out above is a general description of the structure of the product-testing procedure. There will be large amounts of detailed information made available to guide and control the operational practices in testing and certification bodies. Test methods will be detailed in European Standards currently being developed by CEN. A full description of all aspects of testing, assessment and certification will be contained in a detailed "Certification Manual" to be prepared under the supervision of the RG-CPDW, and with the participation of representatives of the Notified Bodies.

4. MANAGEMENT OF THE EAS

4.1. Tasks at the European level

To operate effectively as a single scheme, certain tasks will need to be performed at the European level. These will include:

- Maintenance and continuing development of the Scheme.
- Making available information on the EAS to users and producers.
- Maintenance and updating of Positive, Composition and Approved Constituent Lists (including the evaluation of new substances).
- Updating of test methods and technical specifications.
- Assessment on a "case-by-case" basis of issues referred by Notified Certification Bodies.
- Maintenance of databases of approved products.
- Reviewing the consistent and effective performance of the Scheme.

4.2. Current institutions and roles

The institutional framework being used is primarily that which supports the operation of the CPD, but with additional elements recognising the special features of the EAS relating to the control of drinking water quality as identified in paragraph 3.4.

European Commission

The Commission is responsible for the provision of all professional and administrative services required for the operation of Directives. As regards the CPD, the Construction Unit of the Enterprise Directorate has the general responsibility, and has been undertaking the bulk of the work on the development of the EAS. The Environment Directorate is responsible for drinking water issues, and has been associated with the EAS programme. The development of positive lists for substances used to make organic materials has had reference to the work of the former Scientific Committee on Food. In future the scientific support for the EAS will fall within the remit of the Scientific Committee on Health and Environmental Risks (SCHER)[29].

Supervisory Committees

As outlined in paragraph 1.2, the Standing Committee on Construction and the Standing Committee on Drinking Water have overseen the work on the EAS. The RG-CPDW is an advisory Working Group reporting to both Committees.

Notified Bodies

The work of certification, testing and inspection under the CPD is carried out by Notified Bodies, who are designated by MSs[30]. Some MSs have started the process of

[29] Commission Decision 2004/210/EC

[30] See CPD Guidance Paper A. The designation of notified bodies in the field of the Construction Products Directive. September 2002. Doc. CONSTRUCT 00/435 Rev. 1.

identifying the Bodies likely to be designated in their countries[31]. Such bodies will be expected to work together, participating in the EAS development process, and in particular in the drafting of the Certification Manual. This is to be done using the arrangements provided by the Sector Group of Notified Bodies, and specifically by the creation of a specialist team in the Pipes and Tanks Sector group. The identification and participation of Notified Bodies is now urgently required, and MSs and the Commission need to give priority to setting up these arrangements.

The introduction of revised, and sometimes complex, test methods and assessment criteria, and the likely involvement of notified bodies with limited experience of the range of testing now proposed, will require a programme of training and familiarisation. It will be essential to the status and credibility of the EAS that the certification process is seen to be the same wherever it is carried out. There will be a need to monitor the consistent operation of the EAS across Europe to ensure that it is satisfactory, but MSs will remain responsible for the effective performance of NBs in their territories.

Member State regulators

All MSs have some regulatory capability in order to fulfil their general responsibilities under the DWD. Not all MSs operate their own acceptance schemes, but those that do have the technical and administrative resources in place to operate and maintain their schemes.

CEN and EOTA

CEN, the European Standardisation Committee, is responsible for the preparation of harmonised product standards (hENs). This work is carried out under requirements issued by the Commission in the form of Mandates M131 and M136. CEN is working on product hENs and on supporting standards that set out the test methods to be used for EAS approval.

CEN and the Commission have in place a series of arrangements to monitor and control the preparation of hENs under the CPD. Since CEN's work is particularly closely related to the development of the EAS, special procedures and mechanisms have been established to ensure close co-ordination of the work of all the bodies involved.

EOTA is the European organisation of the MSs' approval bodies responsible for issuing ETAs for construction products deviating from hENs or for which hENs cannot yet be elaborated.

[31] The formal notification can only take place as part of the process of implementing the EAS.

4.3. Future organisation

EAS Management Committee

A new EAS Management Committee will be required to supervise the operation of the EAS. Given that it will primarily involve water regulators, and be concerned with drinking water protection, it is expected that the EAS Committee will be constituted as an advisory Group under the auspices of the SCDW. It will, however, retain links with the SCC for CPD purposes. In addition to oversight of management tasks, the Committee would be responsible for liaison with NBs, CEN and EOTA, and with industry interests.

Commission as Administrator

There will be a requirement for some professional and administrative capability in the Commission to support the tasks referred to in paragraph 4.1 above. This will include the maintenance of both scientific and public databases for the EAS, and the provision of information services, i.e. a web site with different levels of right of access in EC official languages. As with the EAS Management Committee, the principal focus of the work will be on drinking water issues, and so it would seem appropriate for the support unit to be linked with the present Commission unit (within DG Environment) dealing with drinking water and water quality issues.

Member State regulators

MSs will still require some regulatory capability to supervise the operation of the EAS within their countries. The regulators will be expected to participate in the management machinery of the EAS, and to contribute their expertise to its operation. However, those with full acceptance schemes in operation should expect to make significant savings when the EAS is adopted.

Scientific advice

Specialist scientific advice will be needed to support the maintenance of positive lists (particularly the toxicological evaluation of new substances), and on the setting of acceptance levels. Whilst this work will be within the remit of SCHER, it seems unlikely that the Committee will have available to it the capacity to deal with the large number of substances involved.

The EAS Co-ordinating Group, with the assistance of MSs toxicologists is preparing an estimate of the resources needed to provide toxicology support for the EAS. A number of options are being considered, including a proposal based on the current European authorisation process for pesticides, whereby a pair of MSs would assess toxicology dossiers, acting as arbiter in the case of divergent views and providing overall independent guidance.

4.4. Legal basis and resourcing

Chapter 2 pointed out the need to provide an explicit legal basis for the operation of the EAS, and specifically for the creation of the management and administrative capability at European level within the Commission services. An amendment to the DWD is recommended. The following amendments of the DWD could be considered:

- Add a paragraph to Article 10 (Quality assurance of treatment, equipment and materials) stating the requirement for Member States to use materials and products in new installations that confirm with the requirements (acceptance levels) set out in a new Annex IV to the DWD related to the migration of substances into water intended for human consumption (the EAS Positive List, the EAS Composition List and the EAS approved Constituents List) and enhancement of microbial growth.
- Add a paragraph to Article 10 to make it possible to issue Community guidelines for the testing regime (to be drawn in accordance with the committee procedure laid down in Article 12 of the Directive).
- Add a paragraph to Article 11 of the Directive (Review of Annexes) with the obligation for the Commission to adapt Annex IV to scientific and technical progress and to requests to add new substances, compositions and/or constituents to the lists. Such changes shall be adopted in accordance with the committee procedure laid down in Article 12. The scientific input could be delivered by national toxicologists under the umbrella of the Scientific Committee on Health and Environment Risks[32].

This approach seems to provide the additional legal basis needed to implement and operate the EAS. However, it should be elaborated in more detail to fully assess the legal aspects. In doing so, other options may surface.

The Commission will also need to provide organisational plans and a budget for the staffing and running expenses for the new unit. This organisation will need to be in place during the period of implementation, and may have to be strengthened temporarily over the launch period. In order to provide an indication of the scale of resourcing required, the EAS-CG believe that 2 staff will be needed, with an yearly operating budget for *inter alia* meetings, travel costs and daily substance allowances for experts, consultancy services, publications and information services. At this stage it is very difficult to give an estimate of the necessary budget, but it is unlikely that it will exceed 1 million Euros.

[32] This approach has been elaborated by the EAS Co-ordinating Group and discussed with DG SANCO and the RG-CPDW. DG SANCO is the Health & Consumer Protection Directorate-General of the Commission

5. IMPACT ASSESSMENT

5.1. Costs and benefits for regulatory authorities, producers, trade, users and consumers.

In reviewing the impact and cost/benefit of the EAS it is helpful to distinguish the three elements in the design of the EAS as now proposed:

(i) "Conventional" harmonisation under the CPD, excluding the special features of the EAS that are related to the requirements of the DWD.

(ii) Creation of a common regulatory scheme across Europe, going beyond conventional harmonisation to introduce uniform testing and acceptance levels (see paragraph 2.3).

(iii) Introducing practices and levels of acceptance that go beyond current, MS practice to achieve the higher levels of performance required by the tightening standards of the DWD.

Without the full detail of the EAS available, it is impossible to estimate with any precision the costs and savings that will be experienced by the Commission, MSs and by industry. It is anticipated that the final decisions and agreements on the final form of the EAS will be accompanied by a more detailed financial evaluation. This chapter identifies in general terms the nature of the costs and benefits that will arise.

5.2. Harmonisation under the CPD

Development costs and benefits

The substantial costs of the development of test methods and harmonised standards are borne in part by all those industries that participate in the work of the CEN Technical Committees. (This is the same for all sectors under the CPD). The EAS, however, has required a much larger involvement of national water regulators and the Commission than would be normal for the CPD, and they have met the major part of the costs of technical research. The benefit for regulators is the access to "best practice" and the sharing of expertise and financing. This should be especially valuable in those MSs that do not have their own systems at present. These benefits will result in improved consumer protection.

Operating costs and benefits

The maintenance of the EAS itself will involve modest costs for regulators and industries. The costs of testing and auditing will be borne by producers. Insofar as the EAS replaces comparable arrangements in MSs, the costs experienced by producers should not be increased. Indeed, there will be savings for those producers who currently bear the expense of testing in several different MSs. They should also gain from access to the services of Notified Bodies across the EU, which should improve efficiency through competition. However, in those areas where comparable approval systems do not exist, producers will have to meet the extra costs of product testing and certification. This will generally be the case for the auditing and surveillance arrangements of the 1^+ AoC system.

5.3. The EAS as a common regulatory system

Development costs and benefits

These should not be substantially different from those of basic harmonisation, save that more research may be required to establish the common acceptance levels.

Operating costs and benefits

The running of the EAS at European level will require the establishment and funding of a management and administrative capability in the Commission (see paragraph 4.3). When the EAS is established, MSs should be able to reduce significantly costs currently incurred in administering national schemes. The regulators will also benefit from the ability to refer to collaboratively developed assessments of high levels of protection related to DWD Article 10, and this should translate into effective protection for consumers.

The testing costs for producers will be little different to those in paragraph 5.2, except when new substances and metals are put forward for inclusion in PLs and CLs. However, the benefits for producers operating in the wider European market will be maximised if MSs do not adopt different variants of the EAS, since these will involve producers in the costs of tracking MS requirements, additional testing, perhaps varying product specification, and producing more complex product marking information.

5.4. Improving levels of consumer protection

It is clear that the EAS will go beyond the harmonisation of the current approval schemes of MSs. In some cases it will involve the adoption of best practice that has been introduced in only some places. More generally the EAS will be one of the means by which MS respond to the increasingly stringent requirements of the DWD in the future (e.g. the tightening of the lead standard). This is particularly so in the case of the regulation of metallic products, where there are only limited controls in place at present, but where metallic materials are known to be significant contributors to concentrations in drinking water.

Development costs and benefits

These are higher where new requirements are being developed, and are involving substantial commitments of resources by regulators and industry interests.

Operating costs and benefits

The new, and more demanding, tests for some products will impose extra costs producers, certainly in testing and certification, but in some cases also in re-formulation of products. These new tests are clearly aimed at securing higher levels of consumer protection in the future.

However, it should be borne in mind that the EAS is the means to securing DWD compliance, and is not an end in itself. If the EAS were not under development, MSs themselves, together with industry, would need to be addressing the same problems but without the benefit of the pooling of expertise and resources, and with the risk of further proliferation of varying national controls.

5.5. Bearing the cost burdens

Those costs being met by national regulators and the Commission will normally be met from public funds. The costs being borne by industry may eventually be passed to water consumers by way of higher product prices, but in the competitive market it may not be possible always to recover such additional costs, particularly in the short term. This may not be a large problem for high volume or high value products, where development and testing costs may be a relatively small proportion of total cost. However, substantial increases in such costs may pose real difficulties for specialist and low value products, and may also inhibit product innovation. This will require attention to be given to the rules for products assessment, and for the design of transitional arrangements.

6. FUTURE ACTIONS AND DECISIONS

6.1. Implementation and transitional arrangements

Implementing the new EAS will be a complex operation requiring careful planning. Since introduction is not planned before 2008, the work can be developed in line with the discussions and decisions of the RG-CPDW and the SCC and SCDW. However, it is helpful to identify the various areas of work so that those involved are aware of the issues, and planning can be done at the appropriate times.

The Commission, advised by both Standing Committees and the new Expert Group on CPDW, will oversee the processes for planning and implementing the EAS. It is proposed that an Implementation Team carries out the detailed work of managing the implementation. It will be desirable for MS to establish their own planning and monitoring teams to manage the transition.

6.2. Completion of the tasks of the RG-CPDW Sub-Groups[33]

PLCP Sub-Group

- Further work on the addition of substances to the draft PL, and a programme for full evaluation of all listed substances.
- Extension of the PL to the full range of possible materials in contact.
- Procedures for dealing with impurities and reaction products.
- Conversion factors for other product classes.
- Definition of TOC to be used and the analytical performance required.
- Use of TOC to avoid the need to analyse for PL substances.
- Analytical performance required for measuring PL substances.
- Integration of CEN test methods and regulatory procedures for interpretation.
- Recommendation of acceptance levels.

Metals Sub-Group

- Liaison with CEN on test method standards, including a method to translate the outcome of the tests to the acceptance criteria.
- Agreement on the worst-case test waters to be used in the long-term test.
- Verification of the performance characteristics of the standards.
- Provision of information to complete Composition Lists and specifications for reference materials.
- Recommendation of acceptance levels.

Cementitious Products Sub-Group

- Initial ACL and procedure for the addition of new constituents.
- Initial PL.
- Liaison with CEN on test methods.
- Recommendations on acceptance levels.

[33] The Sub-Groups could continue to work under the new Expert Group on CPDW.

The EAS Co-ordinating Group will need (1) to continue its supporting role with respect to the EAS Work Programme and (2) to progress work on some outstanding work items such as the protocols for the assessment of complex products, the recognition of prior approvals (products and materials), determination of the range of items within approved product "families" and limited testing for minor changes in specification.

6.3. Test methods

Further research

The EAS research programme has so far concentrated on the development of new test methods and on the improvement and technology transfer aspects of existing tests. The work of the EAS Sub-Groups and the outcome of the first programme of EAS research have raised other questions that need to be addressed by research. Projects are currently being organised to further develop the testing methods for GCMS and enhancement of microbiological growth. Some other questions must be answered before the EAS can be implemented e.g. what is the performance of long-term rig test for metallic materials and the other new tests for surface characteristics of metals? Can all test laboratories achieve the desired level of reproducibility when applying the test methods to products that are currently on the market? For all new test methods it will be necessary to establish acceptance levels before the EAS can be implemented.

There are other research requirements that can be carried out after the implementation of the EAS e.g. possible enhancements to the current test requirements such as the possible application of developments in toxicity and mutagenicity testing.

TC164/WG3 Work Programme

A Working Group (WG3) of CEN/TC 164, Water Supply, is drafting European Standards. Arrangements have been made for close liaison with the RG-CPDW and the EAS-CG. The WG3 programme is regularly reviewed. WG3 is also associated with the research programmes sponsored by the RG-CPDW and the Commission. There are a number of areas where the RG-CPDW will need to give guidance (and where necessary decisions) to WG3 on the interaction between test methods and regulatory procedures, and on adopting consistent practices. This will include:

- Definition of elevated temperature
- Specification of test waters
- Number of replicates
- Specification of analytical performance
- Interpretation of results
- Ensuring that test methods and acceptance criteria are fully compatible.

It is accepted that the present programme, with its emphasis on approving methods as they become available, will mean that all standards will not, in this first phase of work, be wholly consistent. It is expected that reviews for consistency, and consolidation of more common practices will occur as standards come up for review.

Transposition of ENs and withdrawal of conflicting national standards

In principle, the ENs setting out the test methods to be used by the EAS will follow the normal rules for the withdrawal of corresponding national standards or specifications. However, since the existing standards/specifications will often be intricately incorporated in current MSs acceptance schemes, regulators will be involved in planning the timing of the formal approval, adoption of supporting ENs and withdrawal of conflicting national standards.

6.4. Product Specifications – Introduction of hENs/ETAs

Revision of M136

It will be necessary for the Commission and the SCC to update M136 to cover the full range of products now seen to subject to the EAS, and to decide on its application marginal product types.

Completion of the CEN Work Programme

The large majority of technical specifications required to support the EAS will take the form of hENs. These will be prepared by CEN, which has identified the Technical Committees that will deal with the products covered by the EAS. Working within the provisions of Mandates M131 and M136 the CEN/TCs will be required to modify "voluntary" ENs by the addition of an Annex Z/A (for mechanical characteristics) and an Annex Z/EAS (for fitness for contact with drinking water). The work on which they are engaged falls into three categories:

- Completion of the work programmes for products falling under M131 (Pipes and tanks) and which will also be used for water supply purposes.
- Completion of the preparation of the Annex Z/A under M136 for those products used exclusively for water supply, and where mechanical characteristics are to be harmonised.
- Addition, when it has been produced, to all these hENs of the Annex Z/EAS incorporating the agreed requirements of the EAS. It is planned that this Annex will be added by way of revision, as amendments, or by the use of the Unique Acceptance Procedure. These processes can be completed in shorter timescales than are require for the full approval of ENs

Activation of hENs

The procedures for the adoption, publication and introduction of hENs and ETAs are set out in EC Guidance papers, and particularly Guidance Paper J. Because CE marking for CPDW products can only be introduced when the EAS is in place, it follows that the publication and introduction of the hENs and ETAs must be co-ordinated.

6.5. Completion of the EAS Manuals

Regulatory Manual. This is likely to be derived from the EAS proposal, but should also schedule and record all the legal/regulatory references, guidance and the technical inputs that underpin the EAS[34].

Certification Manual. This will build on the work already done by the Sub-Groups and within CEN. A working group, including NBs, should be established which will need adequate technical and administrative support from the Commission.

Producers Manual. A working group could be established in due course.

6.6. Administrative arrangements

Notification of Certification and Testing bodies, and creation of a specialist forum

See paragraph 4.2.

Activities at the European level

Work will be needed to establish the EAS management machinery referred to in Chapter 4. There will also need to be considerable strengthening of the technical and administrative capability during the implementation phase, and this would be best achieved by early creation of the EAS management capability within the Commission.

Revision of national regulations

As formal decisions are taken by the Commission (after consultation with the SCC and DWD), and legal changes are made by amendment of the DWD by Council and Parliament, there are established procedures for bringing them into operation locally by enactment in national laws.

Introduction of product testing and CE Marking

CE marking of existing CPDW
This area represents a major challenge, since thousands of products in many MSs will need to be CE marked against the new EAS criteria. There will also be the need to approve many products currently on the market, but not always subject to formal processes at present (e.g. some metallic and cementitious products). In order to smooth the workload, the re-certification of currently approved products should be phased in over a period of years linked to existing re-testing arrangements. It may also be necessary to control the extent to which early re-certification is sought by manufacturers, both to manage workload and avoid market distortions.

[34] The EAS Co-ordinating Group could assist the Commission in the preparation of this manual.

Application of the EAS to new products

New products will be offered for CE marking from the start of operation of the EAS. This workload will have to be integrated with the work necessary to CE mark existing products.

In all cases the principle of the "equal opportunity for placing products on the market" shall be taken into account. During the period of transition, no general advantage or disadvantage should arise for any product family related to a specific material. Accepted products may not be considered superior to products awaiting acceptance under the new arrangements.

Provision of public information

There will be a need to provide information producers and users. MSs will have a particular responsibility to produce and disseminate information relevant to their situations. However, all the participants in the process of developing and implementing the EAS will have a part to play in assisting industries and consumers. The proposed Implementation Team would need to take a leading role in the management and co-ordination of an information programme, and the establishment and promotion of information sources e.g. the web site.

Future decisions

Following discussion and adoption of the proposals outlined in this document, there will be two major areas of decision-taking remaining:

- Acceptance levels
- Transitional programmes for testing and re-testing.

Furthermore, the decision taking process at EU level has to be elaborated. This will depend on the choices to be made by the Commission with respect to the legal framework for the EAS, taking into account the EAS Proposal and the opinions of the SCC and SCDW[35].

It is to be expected that a Commission Proposal to amend the Drinking Water Directive will be accompanied by an extended impact assessment (EIA).

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[35] See rules of procedure drawn up by each one of these committees according to the provisions of the relevant directives and the Council Decision 1999/468/EC of 28 June 1999, in particular Article 7(1) thereof.

ANNEX I

European Acceptance Scheme (EAS) Step-by-Step

Attestation of Conformity

STEP	ACTOR	EAS REGULATORY DOCUMENTS AND CEN STANDARDS	COMMENTS
1. Application, with full formulation, production process details and results of non-EAS type testing	Producer	EAS Producer's Manual, harmonised product standards (hEN)	If there is no product standard available, the development of a standard will become a CEN or EOTA working item
2. Check on details of application	Notified Certification Body	EAS Certification Manual	Application is eligible to be taken forward if information is complete.
3. Check on conformity with EAS/PL, CL and/or ACL	Notified Certification Body	EAS lists (PL, CL and ACL) – part of EAS regulations	If in full conformity, then step 4. If not, than producer will be referred to the EAS Administration Facility (Commission) to start evaluation process to add new substance, composition and/or constituent to EAS list
4. Pre certificate auditing of factory control system and sampling for EAS type testing	Inspection Body under responsibility of Notified Certification Body	EAS Certification Manual	Producer could fail quality assurance requirements. In that case certification is not possible
5. Laying down of protocol for EAS testing	Notified Certification Body	EAS Certification Manual	Test protocol depends on product and follows Certification Manual
6. EAS type testing	Testing Laboratory under the responsibility of the Notified Certification Body	Test standards (EN)	
7. Report of test results	Testing Laboratory	EAS Certification Manual	Report submitted to applicant and Notified Certification Body
8. Evaluation of test results. Check against acceptance levels	Notified Certification Body	EAS Certification Manual and EAS list of acceptance levels (part of EAS regulations)	If product fails, than this will be reported to all Notified Certification Bodies and to the EAS Management Committee. No 2nd application.
9. Certification and CE-marking, with EAS logo. Protocol post certificate auditing	Notified Certification Body	EAS Certification Manual and hEN	Publication of certificate issued and addition of the product to the approved products list
10. Post certificate auditing (audit testing)	Notified Certification Body, Inspection Body and Testing Laboratory	EAS Certification Manual	If product fails audit testing: termination of certification by Notified Certification Body. Publication

ANNEX II

ASSESSMENT OF PRODUCTS OR THEIR COMPONENTS MADE FROM ORGANIC MATERIALS[36]

1. Products and materials covered

Examples of products covered are:

- Plastic pipes
- Simple fittings (connectors)
- Parts of complex fittings (valves, meters)
- Sealing rings
- Coatings and linings
- Ion exchange resins
- Repair materials
- Membranes
- Solvent cements
- Adhesives.

Examples of materials from which these products may be made are:

- Polyethylene
- PVC
- GRP
- Rubber
- Polyurethane
- Epoxy resin.

2. General outline of testing

An outline of the overall scheme covering submission of an organic product to the Notified Certification Body and subsequent testing and assessment is given in the flow chart (Parts 1 and 2) at the end of this Annex. This flow chart fits into the Attestation of Conformity Scheme as presented in Annex I.

3. Assessments to be carried out

The assessments to be carried out are:

1. Odour
2. Flavour
3. Colour
4. Turbidity
5. TOC
6. Enhancement of microbial growth
7. Chlorine demand

[36] Based on the draft final report of the Sub-Group PLCP (doc. RG-CPDW 188 rev.1)

8. Drinking water directive parameters as indicated by the formulation
9. Drinking water positive list substances
10. GCMS for unsuspected substances.

The required analytical performance for these assessments will be given in a supporting document.

Normally products must be tested for all of the assessments listed but there can be exceptions, for example, in the case of ion exchange and absorbent resins assessments 2, 6 and 7 are not required.

4. CEN test methods

CEN test methods from CEN TC164/WG3 will be available for:

1. General migration - factory made products (EN12873-1)
2. General migration - site-applied products (prEN12873-2)
3. Water treatment ion exchange and absorbent resins (prEN12873-3)
4. Water treatment membranes (prEN12873-4)
5. Odour/flavour - piping systems (EN1420-1)
6. Colour/turbidity - piping systems (EN13052-1)
7. Odour/flavour/colour/turbidity - storage systems (EN14395-1)
8. Chlorine demand (prEN14718)
9. Enhancement of microbial growth (TC164 WI 164181)[37]
10. GCMS for unsuspected organic substances (TC164 WI 164298)

Instructions on carrying out these test procedures and on interpretation of test results will be given in a supporting document.

The limit values that must not be exceeded will be given in a supporting document.

5. Use of the positive list

Assessment of products and their components made from organic materials will be supported by a positive list. The positive list specifies substances that may be used for the manufacture of organic materials used to produce products intended for contact with drinking water. In order to be specified on the list, a substance must have been approved (after evaluation of specified toxicity data).

The EAS positive list is based on assessed substances at the European level and additional substances specified in MS regulations.

<u>Assessed substances</u>

- Monomers and other starting substances.
- Additives.

[37] WI = Working Item included in the work programme of CEN TC164

Note: Assessed means fully assessed by the SCF[38] and listed in the Synoptic Document and more recently in the so-called Super Directive. The Super Directive will be replaced by the term Super Regulation is due course.

Substances specified in member state regulations or recommendations referring to materials in contact with drinking water

- Monomers and other starting substances.
    - Listed in the Synoptic Document (as substances with insufficient toxicity data).
    - Not listed in the Synoptic Document.
- Additives.
    - Listed in the Synoptic Document (as substances with insufficient toxicity data).
    - Not listed in the Synoptic Document.

Note: Some non-assessed substances could have been assessed by member state toxicologists, but the nature of such an assessment and whether it is equivalent to the SCF assessment, has not yet been investigated (assuming the assessment would be available).

A substance specified in the EAS positive list is permitted to be present in a formulation provided it satisfies any 'restrictions' specified in the list. If a substance is present in a formulation but not specified on a positive list then the product cannot be approved unless further steps are taken as indicated in Part 2 of the flow chart presented at the end of this annex.

The restrictions are migration limits (concentrations), based on the toxicity of a substance that must not be exceeded in consumer's drinking water. The restrictions are normally based on the total daily intake (TDI) of the substance assuming a 60 kg person, consumption of 2 litres of water per day and a 10% contribution from drinking water to a person's exposure to the substance.

The requirements for toxicity data, basically the SCF requirements, for adding a substance to the positive list are specified in a supporting document. [39] The EAS positive list is contained in a supporting document of the RG-CPDW. Positive lists for other types of material, e.g. colorants, silicones, greases and adhesives are under consideration.

If the formulation of a product complies with the positive list, i.e. only substances on the positive list are present, then analysis must be carried out on the migration water (test water after contact with a test sample) from the appropriate CEN laboratory test method to ensure that they do not exceed their restriction. However, TOC measurement may be used to avoid the need to analyse for a positive list substance that a measured TOC level shows cannot exceed its restriction, i.e. it shows that there is not enough organic matter present. This procedure is detailed in a supporting document of the RG-CPDW.

[38] The task of the Scientific Committee on Food is now covered by the Additives Panel of EFSA.
[39] Assumes that the SCHER endorses the SCF requirements.

6. Use of other types of lists

Materials, such as bitumen, water, oxygen, ethylene, that are not amenable to a positive list approach, for various reasons, may be used to produce products intended for contact with drinking water subject to conditions specified in a supporting document.

7. Conversion factors

The purpose of the conversion factors is to enable the results of the experimental migration tests (migration rates) to be used to ensure that a specified acceptance limit will not be exceeded in consumer's drinking water. In order to relate the experimental migration rate to the limit value, two factors (reflecting actual usage conditions) need to be applied:

- An estimate of the ratio of the surface area (S) in contact with a volume (V) of drinking water (S/V dm^{-1}): this is an allowance for the dilution likely in practice. This is the F_g (dm^{-1}) factor (see below).
- An estimate of the contact (or residence) time (days) the water is in contact with the surface area (S): this is an allowance for the accumulation of substance over time. This is the F_o (days) factor (see below).

The conversion factor $F_{go} = F_g \times F_o$.

The estimated concentration in consumer's tap water is calculated from:

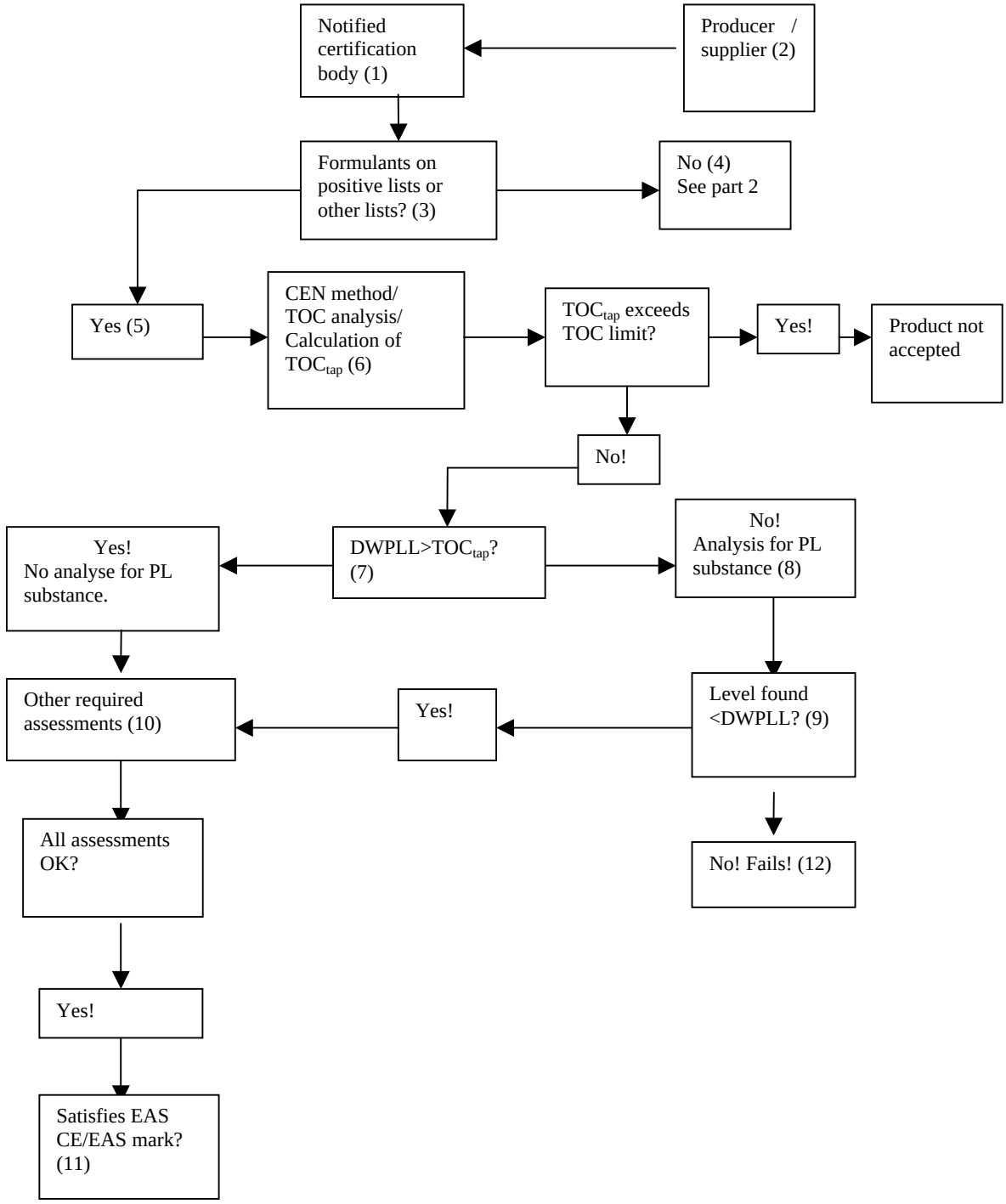
M (daily migration rate - $\mu g.\ dm^{-2}$) x F_{go} ($dm^{-1}.day$).

The conversion factor is used together with the migration rate determined in CEN in the following CEN methods 1, 2, 3, 4 and 5 in paragraph 4 of this annex.

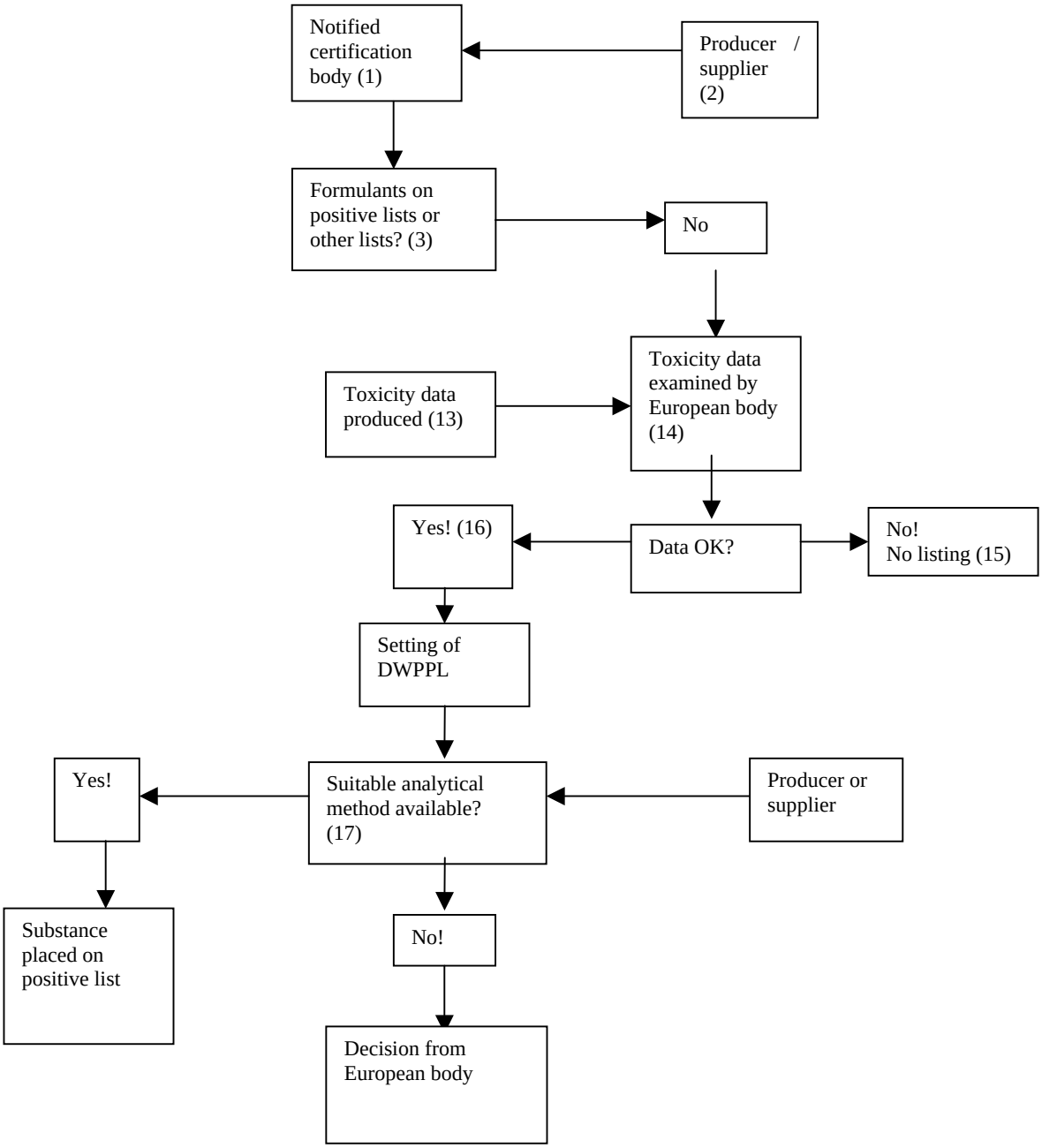
The conversion factors are specified in a supporting document of the RG-CPDW.

With some assessments conversion factors are not possible and the conversion is built into the test conditions, for example 5, 6, 7 and 9 in paragraph 4 of this annex.

ACCEPTANCE PROCEDURE FOR ORGANIC PRODUCTS: PART 1



ACCEPTANCE PROCEDURE FOR ORGANIC PRODUCTS: PART 2



Notes

1. The Notified Certification Body (NCB) will check product conformity against product standards, positive lists etc.
2. Required information supplied by producer and if necessary his supplier (detailed formulation etc).
3. NCB checks substances (and impurities and reaction products - if relevant) in formulation against positive lists
4. If a chemical is not on a relevant positive list then the product cannot be accepted.
5. If a chemical is on a positive list then checks must be undertaken to ensure that it does not exceed its drinking water positive list limit (DWPLL).
6. TOC_{tap} is the estimated level in tap water. It is derived from the migration rate, calculated by using the relevant CEN migration method, and the relevant specified conversion factor (F_{go}). If TOC_{tap} exceeds the TOC limit then the product cannot be accepted. If TOC_{tap} does not exceed the TOC limit then an option is use TOC_{tap} to see if it is impossible for the substance to exceed its DWPLL. Note that the DWPLL would need to be converted to its TOC equivalent.
7. If TOC_{tap} shows that the substance cannot exceed its DWPLL then no specific analysis for the substance will be required.
8. If it does not show this then specific analysis of the substance in the migration water from the relevant CEN test method is required. This calculated migration rate is used in combination with the conversion factor because the DWPLL applies to tap water.
9. If the level found is less than the DWPLL then other assessments are carried out.
10. The other assessments may be carried out in any sequence but it is likely that organoleptic assessments are done first. They may be done prior to step 6 if desired.
11. If all of the other assessments are satisfactory then the product can be given a CE/EAS mark assuming all other CE requirements have been met.
12. If step 9 is not met then the product fails.
13. If a chemical is not on a positive list then the required toxicity data is needed from the producer or his supplier.
14. The European body established to operate and maintain the positive listings will assess this data.
15. If the data is not acceptable then no listing is possible.
16. If the data is acceptable then the European body will set a DWPLL.
17. If the producer or supplier provides a suitable analytical method then the substance can be placed on the positive list.

ANNEX III

APPROACH TO THE ASSESSMENT OF METALLIC PRODUCTS

Summary Report of the Metallic Products Sub Group[40]

The Sub-Group on metals was established by the RG-CPDW to advise on acceptance of metallic construction products in contact with drinking water (CPDW) under the European Acceptance Scheme (EAS). The existing national schemes for CPDW do not include tests for the effects of metallic products on drinking water. The stricter requirements for metals in the 1998 Drinking Water Directive and the need for a level playing field for different product families under the EAS create the need for a European approach to testing of metallic CPDW.

The Sub-Group has reviewed international literature on the testing of metallic products. None of the published national standards or test procedures appears to be directly applicable to the EAS. The Sub-Group concluded that an acceptance scheme must address not only the short-term but also the long-term interaction of metallic products with water. Tests that simulate the in-service use of products should be used. The recommended testing will include the metal elements in metallic products and in metallic components of composite products. Tests for residues of protective films or other surface treatments will be required. Where necessary, testing will be required to determine surface layers.

The Sub-Group has proposed acceptance criteria that are based on parametric values in the DWD, taking into account a contribution of leaching from metallic products in the water supply system. The acceptance criteria may need to apply after a short period of use to allow conditioning of a product by the initial interaction with water.

It is proposed to approve the use of metallic products by reference to lists of accepted compositions of materials (Composition List). This assumes that the long-term behaviour of different products made from the same material with a well-defined composition will be the same. This eliminates the need for long-term testing of each product, provided that each product complies with the defined composition requirements. This Report includes proposals for establishing the list of accepted compositions, including restrictions on use and for making additions to the list of compositions.

Fitness for intended use will follow from:

- verifying that the composition of the material of the product conforms with a material on the Composition List;
- achieving acceptable results from any short-term test needed to confirm the absence of undesirable surface residues.

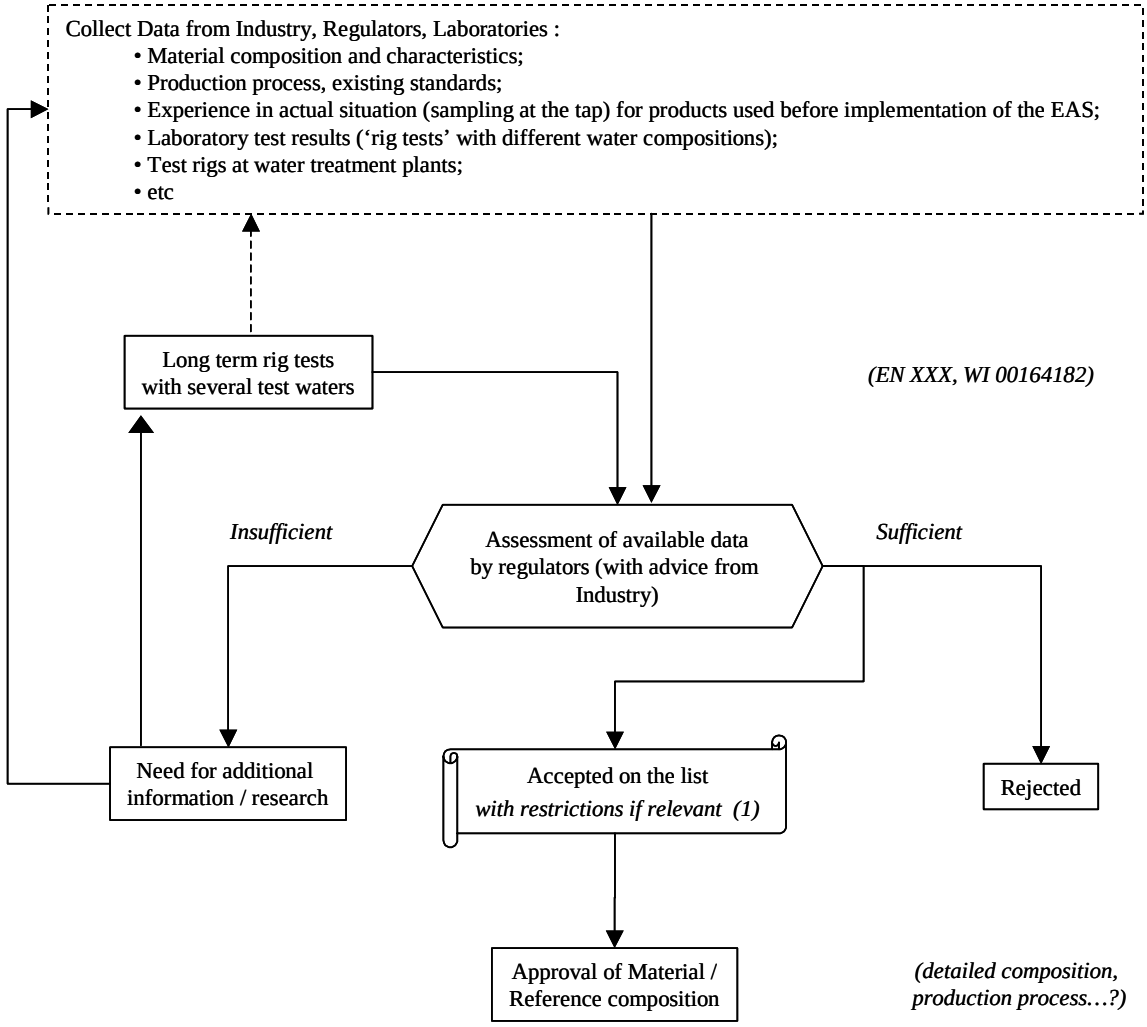
Products that satisfy the test requirements will carry the CE-EAS mark but this will not imply that these products can be used in all locations. Member States will be

[40] See the draft final report of the Sub-Group on Metallic Products (doc. RG-CPDW 190Rev.2_Feb2005)

responsible for identifying the need for restrictions on use of metallic products that are justified on the grounds of incompatibility of the product with a local water composition. The Sub-Group has proposed sampling and analysis protocols that will assist Member States to identify water compositions where restrictions on use of metallic products may be necessary. The Sub-Group has also reviewed formulae relating to the chemical characteristics of water and its corrosion potential towards metals. The Sub-Group considers that formulae can provide guidance on where restrictions might be needed. The actual imposition of restrictions needs to be justified, either by the results of sampling and analysis in the affected area or, by carrying out rig tests at the water supply to the affected area.

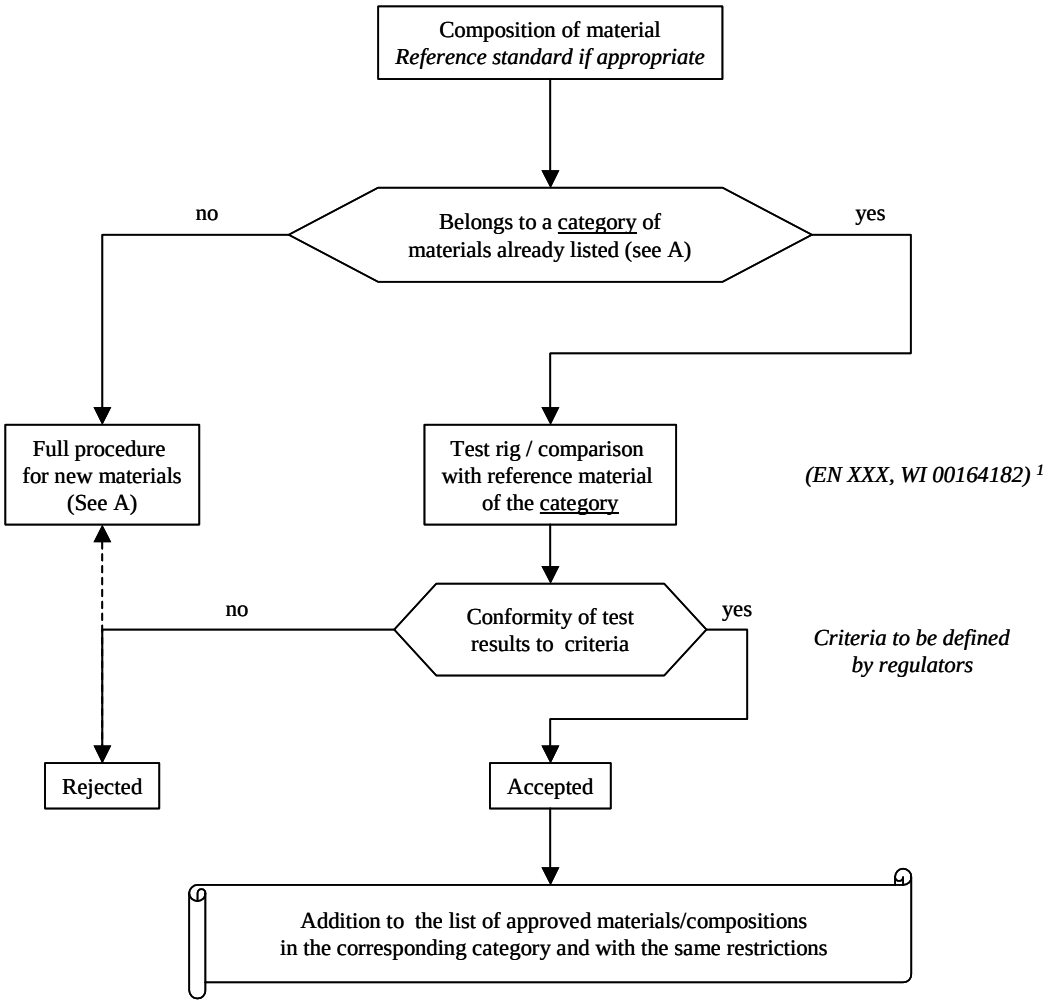
The Sub-Group has also identified those standards that must be developed to support testing and acceptance of metallic CPDW.

Figure A – Procedure for accepting reference Materials for a Category and approval testing of new materials not falling under a listed Category



1 : Possible restrictions regarding :
- intended use (pipes, fittings, ancillaries…)
- limited surfaces / S/V ratios
- surface condition
- water composition

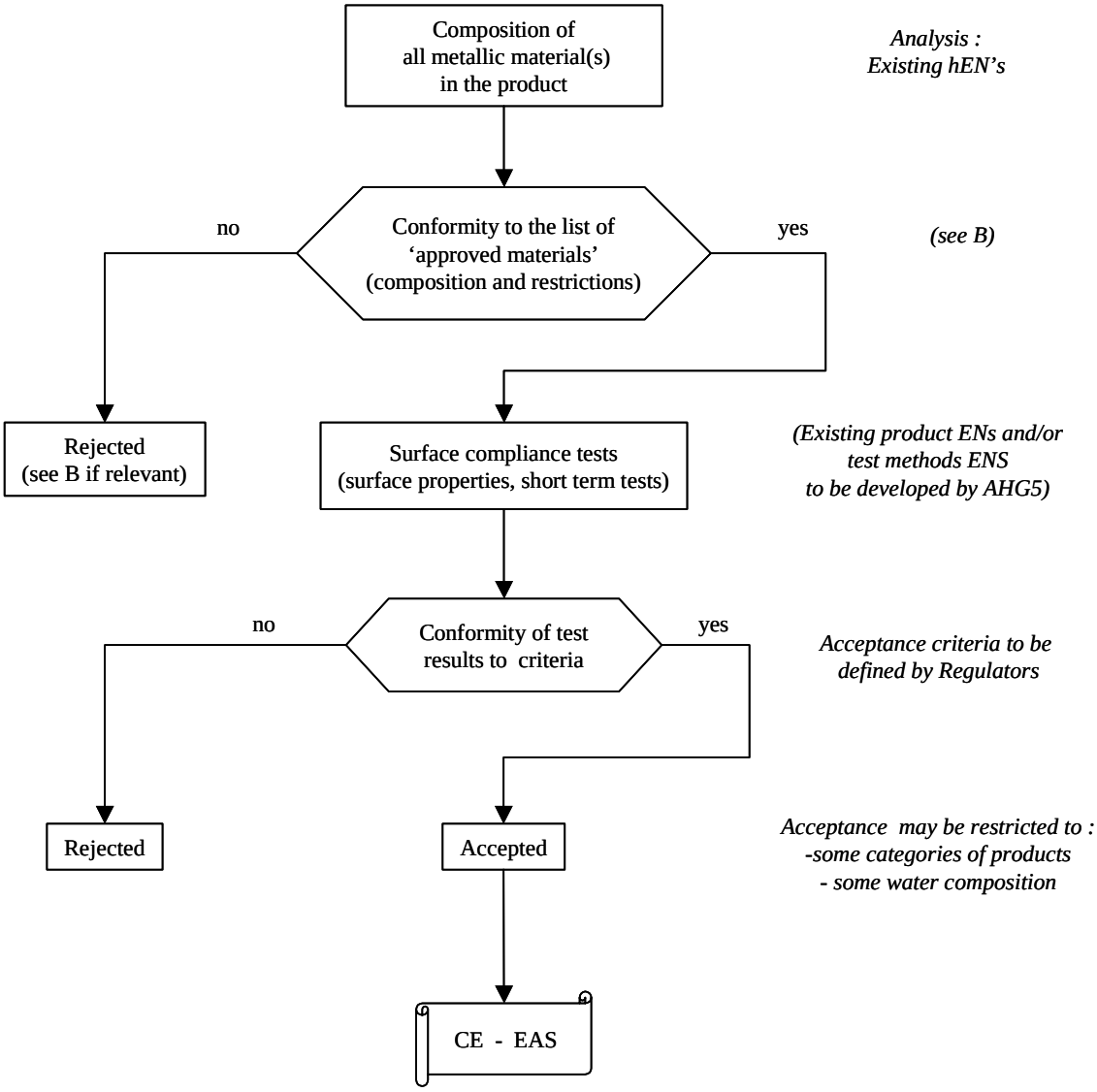
Figure B - Procedure for the addition of a material to the list of accepted compositions



1: Test method to be developed by CEN TC164/WG3/AHG5 and accepted by RG-CPDW for regulatory questions

Figure C - Procedure for accepting products

Note: A product can be made of one or more different metallic materials or of one or more metallic materials in association with organic materials or products



ANNEX IV

APPROACH TO THE ASSESSMENT OF CEMENTITIOUS PRODUCTS[41]

1. General principles

The assessment of cementitious products and cementitious materials is based on:

- the conformity of the composition of the materials and their constituents to:
  - Positive Lists for organic substances (PLs);
  - Approved Constituents List for concrete and mortar (ACL);

- laboratory testing on representative samples where required.

It is not practicable to carry out pre-use testing on concrete and mortar, which is ready-mixed or site-mixed from individual constituents. For this reason protection of public health is achieved by checking conformity of all constituents to the ACL (Route 1, see paragraph 2).

The concept of Approved Constituents List (ACL) has been developed specifically for cementitious products/materials in order to provide the rules and requirements to which each individual constituent has to conform to when it is included in the composition of a product/material in contact with drinking water

The ACL is a list of constituents that are, or can be, used in the preparation of mortars and concretes in contact with drinking water:

- Cement
- Aggregates
- Water
- Additions
- AAmixtures
- Fibres
- Polymer modifiers.

The ACL is held and maintained at the European level (Commission), in consultation with national experts (comitology procedure). It comprises generic types of constituents that are determined as being acceptable for use in cementitious products/ materials in contact with DW. It includes European Technical Specifications (e.g. hENs); where published, to which they conform and any limitations on use of the constituents. Constituents may be added to the ACL if the assessment of its toxicological, hygienic and organoleptic impact on water shows it to be suitable.

The general principles of the ACL and the initial (draft) list are developed in a separate report (subgroup cementitious products/materials).

[41] See draft final report of the Sub-Group on Cementitious Products (doc. RG-CPDW 191 rev.1).

2. ‘Routes’ for acceptance of cementitious products/materials

Depending on the type/specificity of the cementitious product/material, the EAS logo can be delivered through 2 ‘routes’. The requirements for constituents of the material, conformity of formulation to ACL and for the product (testing) are given in next page table.

Route 1 does not include testing of the final product/material; the assessment is based on the conformity of all constituents to the ACL including limitations for organic additives in cement and inorganic additions.

Route 2 includes the testing procedure of the product/material but admixtures and polymer modifiers only have to conform to PLs requirements without specific reference to the ACL.

Applications of route 1 and route 2:

Route 1 is applicable only to concrete and mortar that is ready-mixed or site-mixed from individual constituents all conforming to the ACL.

Route 2 applies in all other cases (e.g. factory made products, pre-packaged cementitious materials, protection and repair materials…).

Table: Principles for acceptance of cementitious products/materials

	Route 1, no testing	Route 2, testing	Observations
A. Formulation of the material			
Conformity to PLs	Yes	Yes	
Conformity to ACL			
o Cement	ACL (Org. Additives < 0,x %)	ACL	*Organic additives on PLs* *Max. content to be revised*
o Inorganic additions	ACL (Org. Additives < 0,x %)	ACL	*Organic additives on PLs* *Max. content to be set up*
o Aggregates	ACL	ACL	
o Admixtures	ACL	PL	
o Fibres - Metallic - Glass fibres - Polymer	 ACL ACL ACL	 ACL ACL ACL	
o Polymer modifiers	ACL	PL	
o Mixing water	ACL	ACL	
B. Product Testing			
Organoleptic parameters	No	Yes	*prEN 14 944 - 1*
General Migration TOC Metals PL substances Unsuspected substance	No	 Yes Yes Yes[1] Yes[1]	*prEN 14 944 – 3*
Enhancement Microbial Growth	No	Yes[1]	

1: Only if the product/material contains organic admixtures and/or polymer modifiers which are not listed

ANNEX V

REFERENCE LIST

RG-CPDW document register on the CIRCA web site, including

- Report of 4MS Feasibility Study (RG-CPDW 001)
- Consultation of the SCC on the approach adopted for the CE Marking of CPDW (RG-CPDW 002 R1)
- Mandate M136 (RG-CPDW 53 R1)
- EC Decision on Attestation of Conformity (RG-CPDW 52 R1)
- EAS on Paper (RG-CPDW 97 R)
- Commission Communication (RG-CPDW 157)
- RG-CPDW Sub-Group reports
  - Positive Lists and Conversion Procedures (RG-CPDW 98 R1)
  - Metallic products (RG-CPDW 190rev.2)
  - Cementitious products (RG-CPDW 191)

Address: http://europa.eu.int/Public/irc/enterprise/Home/main
(Currently available only to RG-CPDW members and observers)

Final reports of the EAS Research Programme 2001-2003

- Assessment of the microbial growth potential of products in contact with drinking water. EU Report 20832 (2003).
- Assessment of migration of non-suspected compounds from products in contact with drinking water. EU Report 20833 (2003).
- Assessment of effect of high level of disinfectants on products in contact with drinking water. EU Report 20838 (2003).
- Assessment of cytotoxicological potential of products in contact with drinking water. EU Report 21397/1 (2004).

Address: http://cpdw.jrc.it/CPDW5-59.htm

From the European Commission Construction website

- CPD Guidance Papers

Address: http://europa.eu.int/comm/enterprise/construction

From the European Commission website concerned with food safety

- Synoptic Document. Provisional list of monomers and additives notified to the European Commission as substances which may be used in the manufacture of plastics intended to come in contact with foodstuffs

Address:
http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/synoptic_doc_en.pdf